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EXAMINER	
CARPENTER, WILLIAM R	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,041	FAGO, FRANK M.	
	Examiner	Art Unit	
	WILLIAM CARPENTER	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9-25 and 35-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-25 and 35-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-3, 14-16, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,354,729 ("Brown").

Regarding Claims 1, 19, and 35, Brown discloses an apparatus for administering a suspendible agent in suspension, the apparatus comprising a delivery container (Figure 1) including a not pictured upstream reservoir holding a propellant fluid, in the instant case the fluid intended to be injected into the apparatus through port (13), an exit port (14), and a delivery mechanism operative for causing the propellant fluid to flow through the fluid path, in the instant case a combination of the inherent pressure under which the fluid is introduced as well as the forces imposed by the interaction between the rotor (1) and the stator (4). Brown further discloses a suspension apparatus (1 and 4 in combination) disposed in the fluid path including a radial flow channel (8) and a plurality of circumferential flow channels (11) coupled in fluid communication by the radial flow channels, wherein the channels are capable of being filled with a suspendible agent and deliver said agent to the exit port after flowing through the radial flow channels and plurality of flow channels when the delivery mechanism is operated to cause the propellant fluid to flow through the fluid path. Brown discloses that the

suspendible agent to be delivered to the exit port via the apparatus to comprise fluids in food, healthcare, and medical applications (Col 9, Ln 54-65). The fluids of the healthcare and medical industries would necessarily include agents suitable for diagnosing and treating medical conditions and the food industry would also consist of suspendible agents used to treat medical conditions such as dehydration, starvation, and hypoglycemia. In the instant case the phrase "suspendible agent" is afforded its broadest reasonable interpretation as "a substance capable of being placed in a suspension with a second undisclosed substance". As such, any fluid within the healthcare, medical, and food industries, which Brown has explicitly disclosed in conjunction with the device, may be considered a "suspendible agent suitable to be administered to a patient to diagnose or treat a medical condition". Additionally, while Brown does not explicitly reference an upstream reservoir, such a reservoir must necessarily exist in order for the device to function in the manner as disclosed by Brown. Brown discloses that material to be mixed “enters through inlet 13 and is drawn radially through flow channels 5” (Col 4, Ln 18-21) and “material is **continually** pumped through the apparatus from inlet 13 to outlet 14” [formatting altered for emphasis]. One in the art would reasonably recognize and appreciate that the device of Brown must be operated in conjunction with some type of reservoir upstream to "continually" provide agent to be mixed.

Regarding Claim 2, Brown discloses a plurality of circumferential dividing walls to define the circumferential flow channels (7).

Regarding Claim 3, Brown discloses gaps within the circumferential dividing walls as to define the radial flow channels (8).

Regarding Claim 14, Brown discloses that the dividing walls include irregularities (owed to their eccentric mounting) that cause the suspendible agent flowing within the flow channels to change direction (Figure 2).

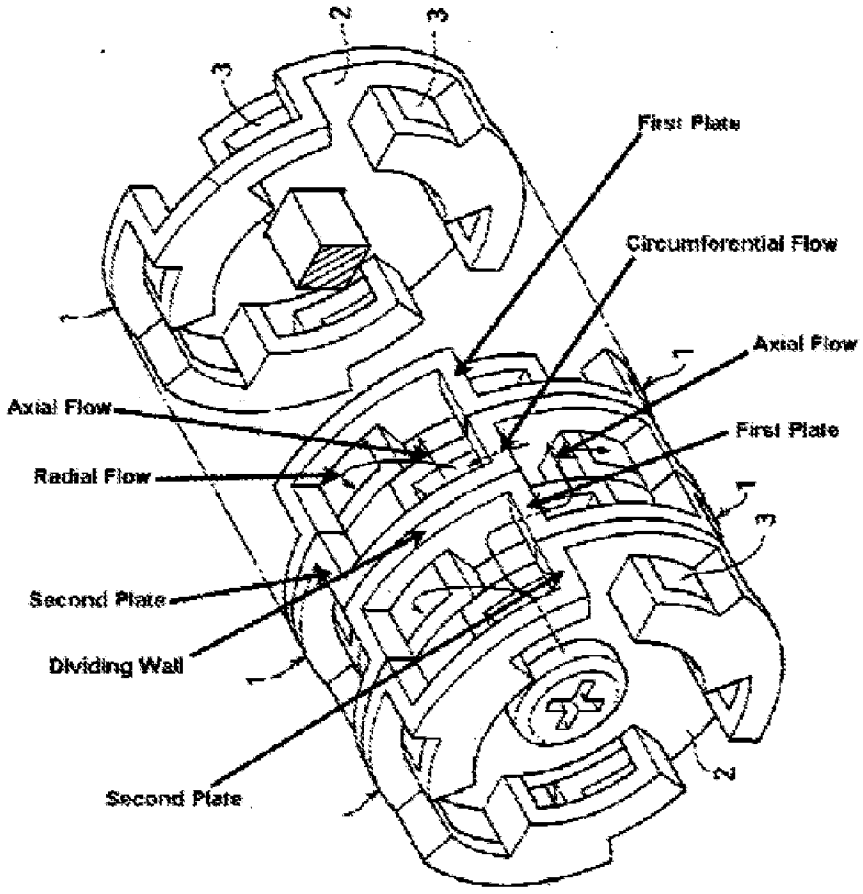
Regarding Claims 15 and 20, Brown discloses that in an alternate embodiment (not pictured) the circumferential dividing walls may be concentrically arranged (Col 8, Ln 11-18).

Regarding Claim 16, Brown discloses that the suspension apparatus includes a pair of first plates (1 and 4) with said plurality of circumferential flow channels and the plurality of radial flow channels being distributed between the plates.

3. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,368,382 ("Kawasaki").

Regarding Claim 19, Kawasaki discloses an apparatus for administering a suspendible agent in suspension, in the instant case concrete or cement (Col 1, Ln 9-13). Kawasaki discloses a delivery container comprising the combination of a cement pump (Col 3, Ln 29-31) and an external compartment comprising a feed pipe (4) having an exit port. Through not explicit, one in the art would reasonably recognize and appreciate that the cement pump as taught by Kawasaki must have access to a reservoir, either integrally formed as part of the pump or as an extension of the delivery container apparatus in a second external compartment, further the pump itself of the feed pipe may be considered to be the reservoir. Kawasaki further discloses a

suspension apparatus disposed within the fluid path (1) including radial flow channels (3; See attached figure) and a plurality of circumferential flow channels (2; See attached figure) coupled in fluid communication by the radial flow channels. Furthermore, it is held to further be inherent that the necessary reservoir for the device contains a propellant fluid in the form of unmixed cement. Claim 19 does not require that the suspendible agent and propellant fluid be of distinct compositions, nor does Claim 19 even positively require said suspendible agent or propellant fluid as a positively required part of the workpiece as claimed. The mechanism of action for the device of Kawasaki includes a cement pump which induces a fluid to flow through the feed pipe (4) and through the suspension apparatus (1). In this manner the unmixed fluid induced to flow by the cement pump acts as a propellant fluid, forcing a quantity of mixed fluid temporarily disposed within the suspension apparatus (the suspendible agent) to be ejected from the apparatus via the exit port. In the instant case the external compartment/feed pipe is held to be an extension of, and therefore a part of, the delivery container and as such the suspension apparatus is held to be positioned within the delivery container.



Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,354,729 ("Brown") as applied to Claim 16 above.

Regarding Claims 17 and 18, Brown discloses the device substantially as claimed except that the device comprises more than two plates wherein a second plate is positioned between a pair of first plates. However, in an alternative embodiment (Figure 5) Brown discloses that the apparatus may be formed as a plurality of first plates with a plurality of second plates (25) sandwiched there between, the plates comprising axial flow channels (28) so as to allow the upstream and downstream surfaces of the plates to communicate. Brown specifically contemplates that the embodiment of Figure 1 could be modified by the increase of additional rotors and stators in order to increase the number of mixing stages (Col 8, Ln 45-49). As such, it would have been obvious for one having ordinary skill in the art at the time the invention was made to stack a plurality of rotor and stator stages of the embodiment of Figure 1, in the manner as illustrated in the embodiment of Figure 5, in order to provide the additional mixing stages contemplated by Brown. In doing so an arrangement of alternating first plates (4) and second plates (1) would be created, separating the plurality of circumferential flow channels and radial flow channels of each first plate from one another via a plurality of second plates having axial flow channels to allow communication between the plates.

7. Claims 4-7, 9-13, 22-25, and 35-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,554,792 ("Hughes") in view of US Patent No. 5,137,369 ("Hodan"), and US Patent No. 4,869,849 ("Hirose").

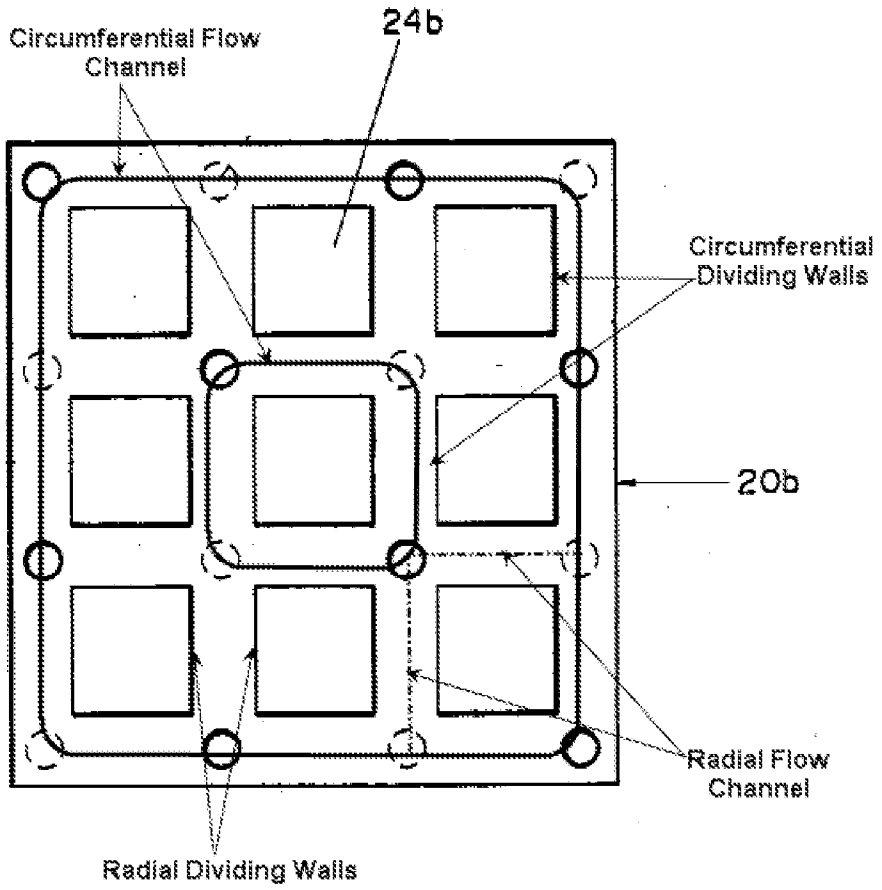
Regarding Claims 4-7, 9-13, 21, 23-25, 35, 38, and 39, Hughes discloses an apparatus (10) for administering a suspendible agent in suspension (Abstract). Hughes discloses the device to comprise a delivery container/syringe barrel (14) including a side wall (36) extending between opposite ends of the delivery container. Hughes discloses the delivery container to have a fluid reservoir (generally 16) holding a propellant fluid (16) and at least partially bounded by the side wall, an exit port (24), a fluid path between the fluid reservoir and the exit port, and a delivery mechanism (58) operative for causing the propellant to flow through the fluid path. Hughes discloses the exit port to be sized and configured for delivery of the suspendible contrast agent (12) from the delivery container to a patient's body via a catheter connected to the luer lock connector (24).

Hughes further discloses the invention to comprise a suspension apparatus (46) defining at least a part of the fluid path and located within the deliver container adjacent to the reservoir such that the fluid path is at least partially bounded by the side wall of the delivery container (Figure 5). Hughes discloses the suspension apparatus to comprise a plurality of circumferential flow channels (12) capable of being filled with the suspendible agent and in fluid communication with the exit port. Hughes discloses that the suspendible agent is delivered to the exit port after flowing through the plurality of

circumferential flow channels when the delivery mechanism is operated to cause the propellant fluid to flow through the fluid path (Figure 5).

Hughes fails to disclose that the suspension apparatus comprises a plurality of plates having upstream and downstream surfaces wherein a plurality of circumferential dividing walls and radial flow channels are disposed. However, such suspension apparatuses are well-known in the art of static fluid mixing as exemplified by Hodan. Hodan discloses a static mixing device (Figure 1) for delivering a suspendible agent in suspension comprising a suspension apparatus comprising plurality of stacked plates (14, 20a, 20b, and 20c) disposed as part of a fluid flow path as to disrupt the flow of a fluid therethrough and mix said fluid (Abstract). Hodan discloses a plurality of first plates (20a, 20b, and 20c) carrying a plurality of circumferential dividing walls (24) defining a concentric plurality of circumferential flow channels (see attached figure) coupled in fluid communication by radial flow channels (see attached figure). In the instant case the term “circumferential" is afforded its broadest reasonable interpretation as "the external boundary or surface of a figure or object" and “radial” is defined as “arranged as to gravitate towards or away from the center of a figure or object". As such the terms “radial” and "circumferential” do not necessitate that the body be circular. However, should Examiner’s arguments not be found persuasive, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the apparatus of Hodan to be of a circular configuration as it has been held that a mere change in shape barring any showing of unexpected results requires only routine and customary skill. Hodan discloses that the device is configured such that the suspendible

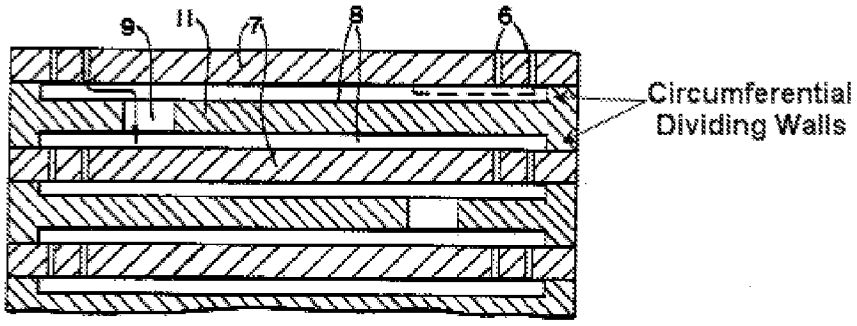
agent would flow to the exit port through the radial and circumferential flow channels when the delivery mechanism is operated to cause the propellant fluid to flow through the fluid path. Hodan discloses that the first plate includes opposed upstream (visible in Figure 1) and downstream (side not visible) surfaces and an axial flow channel (25) extending between the upstream and downstream surfaces. Hodan discloses that the islands that form the circumferential dividing walls also contain sides that form radial dividing walls intersecting the circumferential dividing walls for blocking the flow channels and diverting fluid flow through the radial flow channels (see attached figure). Hodan discloses that axial flow channels may be located adjacent to a center of the first plate (25b) or adjacent a peripheral edge (25a) of the first plate.



As both the device of Hughes and the device of Hodan are explicitly disclosed as being used for the purpose of static mixing within a fluid flow line and the both devices work on a similar mode of action (i.e. altering fluid flow path to mix said fluid; see especially Figures 4 of Hughes), it would have been obvious for one having ordinary skill in the art at the time the invention was made to replace the suspension apparatus of the device of Hughes with a plurality of stacked plates, as disclosed by Hodan, thereby only achieving the expected results of substituting one known inline static mixing device with a suitable alternative to obtain a predictable outcome. In the instant case the device of Hodan utilizes a circumferential barrier to form the outer edge of the plates. However, it would have been obvious for one having ordinary skill in the art at the time the invention was made to utilize the outer wall of the delivery container as the outer edge of the plates, as illustrated by Hughes (Figure 5), in order to reduce the quantity of material necessary to form the plates.

Hughes, as modified by Hodan, fails to explicitly disclose if both the upstream and downstream surfaces comprise the plurality of the dividing walls, only explicitly illustrating the upstream surface to include said walls. However, Hirose discloses a similar inline static fluid mixing device (Figure 1) comprising a plurality of plates (11) disposed within a delivery container. Similarly to Hodan, Hirose discloses the plates to have dividing walls (not labeled) for separating the plates from one another and established fluid flow channels (8) therebetween with axial flow channels (9) interlinking the them. Differing from Hodan, Hirose discloses these dividing walls to be disposed on both the upstream and the downstream surfaces of the plates (Figure 4) with pairs of

flat second plates (7) having axial flow channels (6) interlinking the pairs of first plates (Figure 4) in order to achieve a tight fluid seal.



It would have been obvious for one having ordinary skill in the art at the time the invention was made to modify the suspension apparatus of the modified device of Hughes to comprise a configuration of first plates having the dividing walls on opposed upstream and downstream surfaces and sandwiched between second flat plates, as disclosed by Hirose, thereby only achieving the expected results of substituting one well-known plate configuration in an inline static fluid mixer for another

Regarding Claim 22, Hughes in view of Hodan and Hirose discloses the invention substantially as claimed except for explicitly disclosing that the ratio of volume of the flow channels to a volume occupied by the dividing walls is from approximately 0.25 to approximately 0.5. However, it would have been obvious for one having ordinary skill in the art at the time the invention was made to form the ratio of fluid flow channels to dividing walls of the modified device of Hughes to be within the range of 0.25 to 0.5, since it has been held that discovering the optimum or workable range of a result effective variable involves only routine skill in the art. The geometry of a fluid flow path is recognized as directly affecting the characteristic fluid flow therethrough.

Regarding Claim 36, Hughes discloses the device to comprise a delivery component (in the instant case a catheter, generally observable in Figure 2) connected to the luer lock (24) of the exit port to provide a delivery passageway between the delivery container and the patient's body such that the suspendible contrast agent is delivered from the exit port to the patient's body.

Regarding Claim 37, Hughes discloses the delivery container to comprise the barrel of a syringe, wherein the suspension apparatus is located within the barrel (Figure 5).

Regarding Claim 40, Hughes discloses the propellant fluid to comprise any viscous fluid that is biocompatible, such as normal saline, water, buffer, or a contrast agent that is different from the contrast agent (12; Col 3, Ln 50-55). It is of importance to note that "contrast agent" is not even a positively required part of the workpiece as claimed.

Response to Arguments

8. Applicant's arguments filed 23 December 20008 have been fully considered but they are not persuasive or are moot in view of the new ground(s) of rejection.

Applicant argues that "Brown is devoid of any disclosure of 'a suspendible agent suitable to be administered to a patient to diagnose or treat a medical condition'". This is not persuasive. Brown clearly discloses that the device should be used with fluids in the industries of food, healthcare, and medical and such fluids may be considered to be part of the disclosed workpiece. Applicant appears to be inappropriately narrowing the

definition of “suspendible agent” as part of Applicant's argument. However, as previously iterated, with respect to the claims the phrase "suspendible agent" is afforded its broadest reasonable interpretation as "a substance capable of being placed in a suspension with a second undisclosed substance”. Applicant’s use of the suffix “ible” clearly indicates limiting the agent to a suspension as functional language drawn towards the intended use of said agent. The food, healthcare, and medical fluids taught by Brown in conjunction with the device need not explicitly be disclosed as being part of a suspension, rather only the ability of said fluids to be part of a suspension is necessary as to satisfy the metes and bounds the claims. Any fluid is "capable of being place in a suspension" with some undisclosed second fluid. For example, any water based fluid may be placed in a suspension with an oil based fluid, or vice versa. For any fluid within the areas of food, healthcare, and medicine disclosed by Brown there is a suitable fluid in which the first fluid will not dissolve. As a mixing device, the device of Brown is clearly capable of delivering said “suspendible agent” in suspension.

Applicant argues that “Brown does not disclose an apparatus including a fluid reservoir holding or capable of holding a propellant fluid”. However, this is not persuasive. Examiner may rely not only on what is explicitly stated in the prior art, but also what is implied by said prior art as read by one having ordinary skill in the art. Based on the disclosure of Brown one of ordinary skill would reasonably recognize and appreciate that the device of Brown must include some form of reservoir in order to be operated in the disclosed manner. In the instant case the phrase reservoir is afforded its broadest reasonable interpretation as “a part of an apparatus in which a liquid is held”

and as such covers not only hoppers, feeders, and tanks but also fluid conduits and the like. Brown explicitly discloses that material to be mixed "enters through inlet 13 and is drawn radially through flow channels 5" (Col 4, Ln 18-21) and "material is **continually** pumped through the apparatus from inlet 13 to outlet 14" [formatting altered for emphasis]. In order for a material to be continually pumped through the apparatus a continual supply must be introduced through the inlet. One of ordinary skill would recognize that such a continual supply would require access to a reservoir. Furthermore, Brown discloses the device to include an "injection point" (31) to allow the introduction of additional materials. Brown's use of the functional word "injection" necessitates some type of reservoir in order to introduce the substance under pressure as to qualify as an “injection”. While such a reservoir is not shown, or even explicitly disclosed, it is necessary for the device of Brown to function as disclosed.

Applicant argues that “Brown’s device could be used without a reservoir, and a reservoir in not necessarily present”. This is not persuasive. Merely because Applicant can modify the disclosed operation of the device of Brown such that a reservoir is not necessary as part of the process of use does not obviate the disclosure of Brown. As discussed above, as Brown discloses that material is “continually” pumped through the apparatus, requiring the material to be continually introduced to the inlet, such disclosed use necessarily requires the presence of a reservoir. A fluid can not be introduced to said inlet, particularly in a continual manner, without passing through some sort of reservoir; for example a conduit, a tank, or some other form of holding container. As

such, in order to function in the manner disclosed by Brown, a reservoir is a necessary part of the disclosed workpiece.

Applicant argues that “Brown does not disclose that causing the propellant fluid to flow through the fluid path would deliver the suspending agent to the exit port”. This is not persuasive. Examiner may rely upon not only that which is explicitly stated in the prior art, but also that which is inherent. The nature of fluid flow is such that upstream particles interact with downstream particles, apply force thereto imparting motion to the downstream particles independent to any supplied pumping force. This is particularly relevant in a mixing device such as Brown that significantly alters fluid flow creating turbulence. Furthermore, the fact that the propellant fluid would be mixed with the suspendible agent, as acknowledged by Applicant, the propellant fluid can be conceived to be a carrier fluid, delivering the suspendible agent to the exit port. Additionally, contrary to Applicant’s insistence a causative relationship between the delivery mechanism "causing the propellant fluid to flow through said fluid path” and the suspendible agent being "delivered to said exit port". In Claims 1 and 19 Applicant uses the phrase "**when** said delivery mechanism is operated to cause the propellant fluid to flow through the fluid path” [formatting altered for emphasis]. The "when" clause indicates a temporal relationship between the two events, but does not clearly indicate whether said relationship is causal (the propellant fluid displacing the suspendible agent), correlative (a common root cause for the flow of both the propellant and the suspendible agent), or merely coincidental (the two events being unrelated but happening during the same temporal period). It is important to note that Applicant’s

insistence that the propellant fluid not mix with the suspendible agent can not be found in the claims, or even in Applicant's disclosure.

Applicant argues that "Brown's mixer acts on a discrete quantity of material without the need for any continuous flow". This is not persuasive. While Applicant may be able to envision a scenario where Brown's mixer is utilized to mix a discrete quantity of material, this is contrary to the manner in which the device of Brown is disclosed as being used. Brown explicitly discloses that "[i]n this way, material is **continually** pumped through the apparatus from the inlet 13 to outlet 14 simply by rotation of the rotor ring 7" [formatting altered for emphasis]. As such, it is clear that the device of Brown, when used as disclosed, is not intended to be used to "mix a discrete quantity of material", but rather is intended to be used to mix a continual flow of material, wherein in the instant case the upstream quantity of fluid is considered the propellant fluid.

Applicant agues that, "Examiner fails to point to any specific reservoir structure of Kawasaki". This is not persuasive. In Paragraph 3 of the Detailed Action mailed 03 September 2008 Examiner clearly indicates that "**the pump itself or the feed pipe may be considered a reservoir**" [formatting altered for emphasis]. Examiner at no point asserts that the device of Kawasaki "would reasonably use a reservoir", only that one skilled in the art would "reasonably expect and appreciate that the cement pump as taught by Kawasaki et al. **has access to a reservoir**" [formatting altered for emphasis].

Applicant argues that "Kawasaki's device is not suitable for administering a suspendible contrast agent in suspension". This is not persuasive. The device of Kawasaki is described as a fluid handling device, a "suspendible contrast agent" is a

fluid and as such could be suitably directed through the device of Kawasaki, should one have the proclivity to use the device in such a manner. While Examiner recognizes that "cement paste is not a contrast agent", Examiner notes that the "contrast agent" is not a positively required part of the workpiece as claimed, but rather a recitation of intended use. While the structure of the device of Kawasaki has not been specifically oriented to accommodate a contrast agent, the wall panels will redirect fluid flow mixing the contrast agent and delivering said contrast agent in suspension. Furthermore, the very act of the wall panels actively mixing the contrast agent is not a positively required part of the workpiece as claimed. The claim only requires the contrast agent to be delivered "in suspension" and makes not reference, either explicit or implicit as to what causes the contrast agent to be mixed. As such, even supposing that the device of Kawasaki would not cause some mixing of the contrast agent, a position that has not been provided with evidence, a "suspendible contrast agent" already is suspension could be introduced into the system thereby satisfying the metes and bounds of the claims.

Applicant agues that, "Brown is directed towards mixing, not to administer [sic] and agent, and Brown's device is configured for dispersive and distributive mixing. Thus, Brown is nonanalogous art". This is not found persuasive. Applicant's claimed invention and the device of Brown are both generally related to mixing, i.e. "delivering a suspendible agent in suspension". Claims 17 and 18 do not include any limitations that cause the claims to deviate from this general principal. Applicant's reference towards, an apparatus "suitable to administer a suspendible agent **to a patient** to diagnose or treat a medical condition" [formatting altered for emphasis] is not only functional

language merely drawn towards the intended use of the device, but are not even mentioned in the claims. Modification of the device of Brown is not intended to make the device suitable for administering a suspendible agent to a patient, but rather towards improving the ability of the device to mix a fluid based on suitable known techniques. Such modifications recited by the claims are not exclusive to Applicant's intended use of the device to modify a contrast agent.

Applicant argues that, "Kawasaki's mixer is configured for mixing cement. Thus, Kawasaki is non-analogous art." However, it is important to note that the "suspendible contrast agent" is not a positively required part of the workpiece claims for which the reference of Kawasaki is applied. Furthermore, there is nothing to suggest that the dimension recited in Claim 22 would be exclusive to a contrast agent. One having ordinary skill in the art would reasonably arrive on such dimensions during a process of routine and customary experimentation in order to optimize the mixing properties of the device of Kawasaki, as the number and size of the various channels would be recognized as a result effective variable. Applicant has not shown any evidence that the proposed ratio would not be suitable for the mixing of cement. The geometry of a fluid flow path is recognized as directly affecting the characteristic fluid flow therethrough. Such modifications recited by the claims are not exclusive to Applicant's intended use of the device to modify a contrast agent.

Applicant argues that "Hodan is directed to a static mixing device for homogenizing molten polymer. Thus, Hodan is non-analogous art. A person of ordinary skill would not look to Hodan's device, for mixing molten polymer, to administer a

suspendible agent is suspension as claimed." This is not persuasive. Firstly, it is important to note that said “suspendible agent” is not even a positively required part of the workpiece as claimed, but rather a recitation of intended use of the device. As such, the device of Hodan need only be suitable for such a task. Secondly, said polymer may be reasonably considered a “suspendible agent” or even a suspension. Thirdly, the device of Hodan is specifically related to a static mixing device, an area that includes the requisite mixing required for various "suspendible agents". It is held that the disclosure of one mixing device would be directly applicable to another mixing device.

Applicant argues that “Hodan does not teach, suggest, or motivate a delivery mechanism for causing a propellant fluid to flow through the fluid path”. This is not persuasive, Hodan inherently includes a delivery mechanism configured to cause the polymer through the fluid path, such a delivery mechanism is suitable for delivering an unclaimed “propellant fluid”. Functional language drawn towards the intended use of the device merely necessitates that the prior art be capable of performing such a function, and no explicit teaching is required. Furthermore, the upstream quantity of the polymer itself may be considered a propellant fluid, since said fluid will inherently displace the downstream fluid, thereby acting as a propellant.

Applicant argues that “Hodan’s inlet 11 is not a fluid reservoir; rather, it is a fluid inlet”. However, Examiner submits that the two terms are not mutually exclusive from one another. As has been previously iterated the accepted definition of reservoir is “a part of an apparatus in which a liquid is held”. The inlet of the device of Hodan holds a liquid, and is therefor a reservoir. Applicant appears to rely an unsupported narrowing of

the definition of "reservoir" in an attempt to distinguish the claimed device over the prior art.

Applicant argues that "Hodan does not state the mechanism by which molten polymer enters the static mixer". However, it is inherently necessary that such a mechanism exists. Examiner may rely upon not only what is explicitly disclosed, but also what is inherent to a particular disclosure. Furthermore, based on the disclosure of Hodan, one skilled in the art would reasonably recognize and appreciate that the inherent delivery mechanism must comprise a source of pressure in combination with gravity to propel said fluid through the mixing device.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM CARPENTER whose telephone number is (571)270-3637. The examiner can normally be reached on Monday through Thursday from 7:00AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Carpenter/
Examiner, Art Unit 3767
02/12/2009

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767